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Certified by



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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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	TITLE OF THE INVENTIO	N (500 charac	ters max)			
Chromium Complex Combination						2258
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ENC	LOSED APPLICATION P	ARTS (check	all that apply)			
Specification Number of Pages 2      Drawing(s) Number of Sheets      Application Data Sheet. See 37 CFR	1.76		CD(s), Number Other (specify)			
METHOD OF PAYMENT OF FILING FEES	FOR THIS PROVISIONAL	APPLICATION F	OR PATENT	· · · · · · · · · · · · · · · · · · ·		
Applicant claims small entity status. See 37 CFR 1.27.  A check or money order is enclosed to cover the filing fees.  FILING FEE Amount (\$)					¯	
The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 502191					0.00	•
Payment by credit card. Form PTO-2	2038 is attached.	<u>.</u>				
The invention was made by an agency of to United States Government.  X No. Yes, the name of the U.S. Government.				y of the		
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SIGNATURE  TYPED or PRINTED NAME Martin Fessenmaier			Date 10/15/03  REGISTRATION NO. 46697			
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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Pr visi nal Application, Commissi nerf r Patents, P.O. B x 1450, Alexandria, VA 22313-1450.

#### **CHROMIUM COMPLEX COMBINATION**

#### Field of The Invention

Nutritional supplements.

## **Background of The Invention**

Numerous chromium-containing compositions are well known in the art, however, all or almost all of them suffer from one or more disadvantages. Most significantly, certain chromium-containing supplements are embroiled in toxicity issues (e.g., Cr-picolinate) or have only relatively low solubility and/or bioavailability. Such difficulties may be even further compounded where chromium-containing supplements are combined with other nutritionally valuable compositions. Therefore, there is still a need to provide improved compositions for nutritional supplements that comprise chromium in a nutritionally significant amount.

### **Detailed Description**

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The inventors contemplate that chromium-containing water-soluble matrices may be advantageously combined with a variety of other nutritional supplements, wherein such combinations exhibit additive, or even synergistic, effect with respect to their intended effect. Particularly preferred chromium-containing water-soluble matrices are described in our copending provisional application with the serial number 60/501660 (entitled "Improved Nutraceutical Chromium Complexes with Enhanced Biological Activity and Safety"), which was filed September 9, 2003, and which is incorporated by reference herein.

Especially preferred combinations of such chromium-containing water-soluble matrices include those in which the combinations are intended to positively affect the metabolism of a person. For example, it is known that chromium positively influences glucose utilization.

Therefore, all known nutritional supplements for improving glucose utilization are especially contemplated herein. Similarly, chromium is also known to improve insulin sensitivity.

Therefore, all known nutritional supplements for treatment or prevention of diabetes are especially contemplated suitable for use herein. Furthermore, chromium has also been implicated in prevention and/or improvement of elevated cholesterol. Consequently, all known nutritional

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supplements for treatment or prevention of heart disease or elevated cholesterol are especially contemplated appropriate. Still further, it is known in the art that chromium may also have an anabolic effect. Therefore, all known dietary supplements for increase of muscle mass are considered suitable for combination with contemplated chromium-containing matrices.

Exemplary suitable combinations of chromium-containing matrices include combinations with cytokinins (e.g., to reduce cholesterol, and/or improve glucose uptake). Preferred methods and compositions are described in our co-pending provisional applications with the serial number 60/499637 and docket number 22247/10600, filed August 8, 2003, both of which are incorporated by reference herein. Further particularly preferred combinations include those in which chromium-containing matrices are combined with metabolic enhancers, and especially conjugated linoleic acid (CLA). Yet other preferred combinations include those in which an anabolic agent (e.g., DHEA) is combined with preferred chromium-containing matrices.

Thus, specific embodiments and applications of improved chromium complex combinations have been disclosed. It should be apparent, however, to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the spirit of the present disclosure. Moreover, in interpreting the specification, all terms should be interpreted in the broadest possible manner consistent with the context. In particular, the terms "comprises" and "comprising" should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

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